Pushing the Limits – The Next AVATAR

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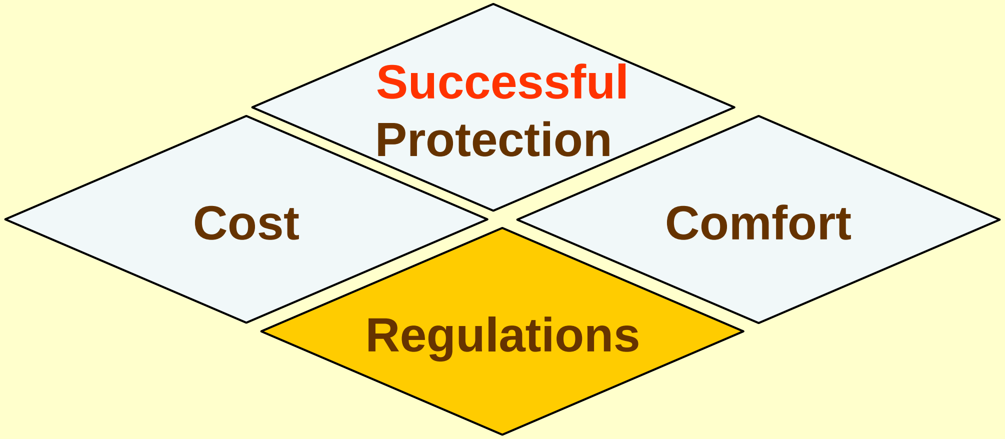
Overview of Presentation

- Respirator Design: Drivers
- The Challenges: Design and Real-World
- The Opportunity: Creating the Next Avatar
- Need for Innovation and Systems Approach
- Quality Function Deployment
  - User Needs → Product Design – The Key Steps
- Building The *House of iRespirator*
- The Path Forward

Respirator Design: The Drivers



Preparing for an Influenza Pandemic:
Personal Protective Equipment for Healthcare Workers
-- IOM Report, September 2007

The Three Perspectives

- End Users
  - Successful Protection
  - Comfort
- Administrators/Providers
  - Successful Protection
  - End User Acceptance
  - Cost
  - Regulations (e.g., OSHA)
- Manufacturers
  - End Users
  - Administrators
  - Regulations (e.g., NIOSH)
- *Trade-Offs – The Balancing Act*

The Design Challenges

- Ensure Performance
  - Efficacy – Ensure Successful Protection During Use
  - Avoid Leakage [Crutchfield et al., 1999]
    - Fundamental – Occurs When Donned
    - Transient – Occurs during Use
- Ensure Comfort
  - Enhance Compliance with Usage of Device
- Maintain or Reduce Total Cost of Ownership (TCO)
  - TCO = Respirator Cost + Fit-Testing Cost + Disposal Cost + …

The Real-World Challenges

- Limitations of Current Generation of Respirators
  - Facial Profiles
    - Beard, Children, …
  - Need for Fit-Testing
    - Cost, Time, Compliance, …
  - Disposable – Environmental Impact
- Potential Shortages (e.g., H1N1 Pandemic)
  - Manufacturers Running at Full Clip
  - Fortunately, it was, “The Flu Season that Fizzled.”
    - » *The Wall Street Journal*, March 2, 2010

Cal/OSHA Recalls 3M 8000 Respirators

- California Department of Public Health (CDPH) and Cal/OSHA
  - 3M 8000 – Low Success Rate in Fit-Testing
  - CDPH
    - Withhold Further Shipments
    - Stop Providing them to Healthcare Facilities
- While Cal/OSHA is not prohibiting use of the 3M 8000 per se, it strongly recommends against using this model for prevention of aerosol transmitted disease and urges employers, if they decide to issue a respirator of this model to any employee, to assure a successful fit test with that employee.

January 2010

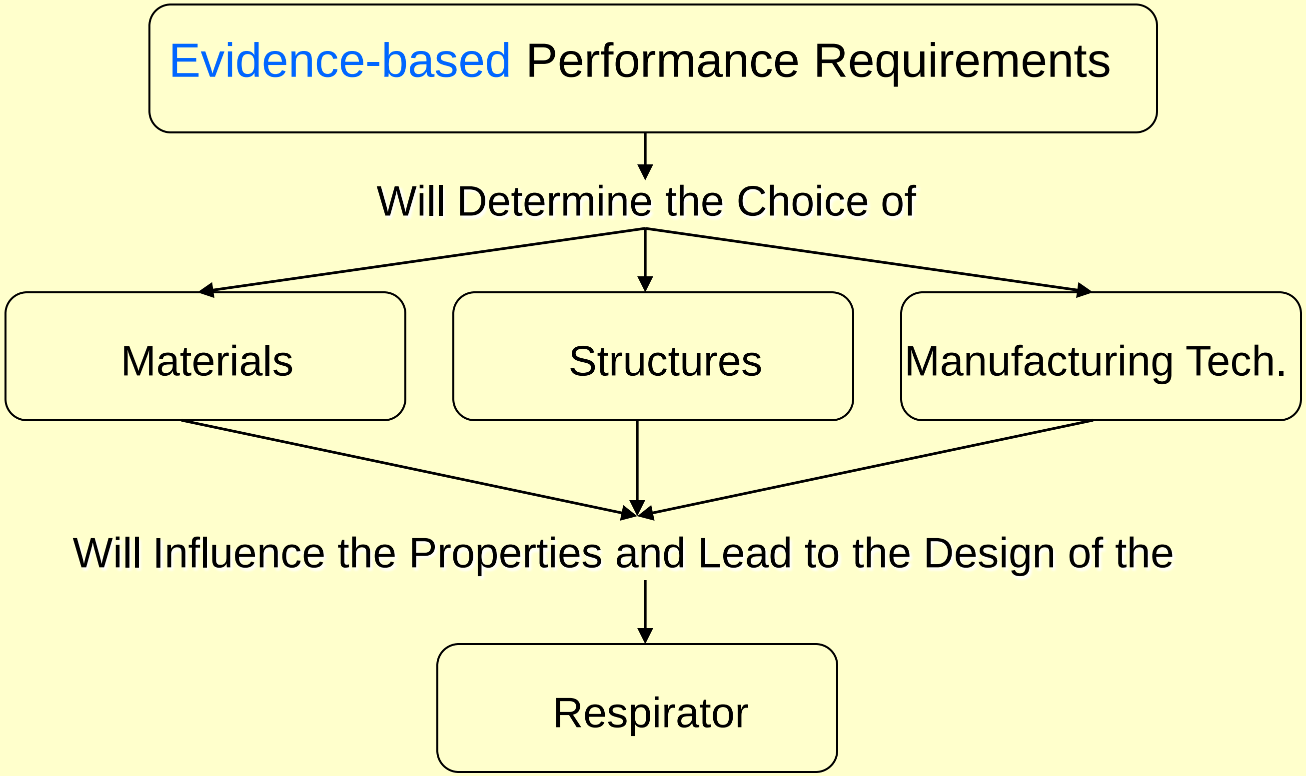
The Opportunity

Creating the NextGen Respirarator,
Rather the Next Avatar …

What Does it Mean …

- Push the Limits, The Avatar Way ...
- Harness Advancements in Technologies
  - Understanding User Needs
  - Materials
  - Structures
  - Manufacturing Methods
- Result: The *i*Respirator (With Apologies to Steve Jobs)

The Design Toolkit



Gather Evidence from Users …

What is Needed: The Twin Catalysts

- Innovation
- A Systems Approach

Innovation – A Hot-Off-the-Press View

George Buckley on Innovation at 3M

- Innovation: In Tweaks and Snips
  - Making Respirators Cheaper
  - Manufacturing Process
    - Quadrupling in Speed and Efficiency
- Cost-Centric Innovation
- The Box Office Hit – The Oscar Jingle …

•*The Wall Street Journal*, March 1, 2010

Innovation: The *Oxygen* for Respirator Design

Inspiration

Necessity

Neat

Original

Valuable

Applicable

Timely

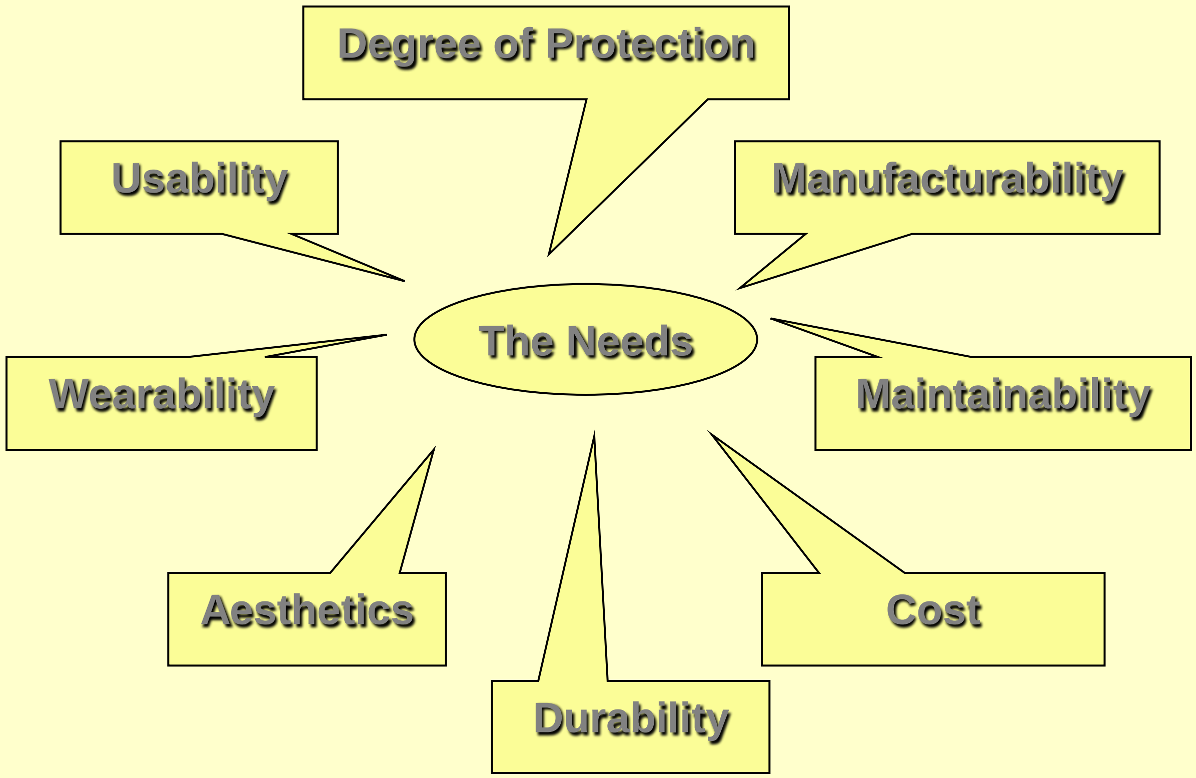
Intelligence

Outstanding

Novel

FUN!

What are the User's Needs?



Needs are in the Language of the Users – Subjective, Easy to Express

Transforming Needs to Reality ….

- What Does “Usability” Mean?
- What Does “Durability” Mean?
- …..

Making it Happen: Need for a Systems Approach:

Quality Function Deployment (QFD)

Quality Function Deployment

- *A method for developing a design quality aimed at satisfying the consumer and then translating the consumer's demand into design targets and major quality assurance points to be used throughout the production phase. –Akao, 1990.*

- Encompasses The Complete Lifecycle
- Subjective Attributes to Quantifiable Parameters
- Facilitates the “Engineering” or “Realization” of Needs

The QFD Process

Understand the Needs – The What (Subjective)

Prioritize the Needs – (Scale of 1 – 5)

Map Needs to Measurable Parameters – (Metrics)

Assess the Competition – (Benchmarking)

Define the Specifications – (The Target Values)

Realize the Design – (Materials & Manufacturing Methods)

The Result → The *i*Respirator

Applying QFD to Respirator Design …

Step One: Define the Requirements (Subjective)

Evidence-Based Performance Requirements

Functionality

- Protect against influenza virus
- Guard against contact with contaminated fluids and aerosols

Usability

- Maintain biomechanical efficiency and sense of touch and feel
- Odor-free
- Hypoallergenic
- Accommodate wide range of users (face and body profiles)
- Compatability across various elements of the PPE ensemble and with other equipment (e.g., stethoscope)
- Non-startling to patients and families
- Facilitates communication with others (verbal, facial)

Comfort and Wearability

- Comfortable—no skin irritation or pressure points
- Prolonged use without discomfort
- Breathable—air permeable
- Moisture absorbent—wickability
- Low bulk and weight
- Dimensional stabiltiy
- Easy to put on and take off (don and doff)

Durability

- Adequate wear life
- Strength—tear, tensile, burst
- Abrasion resistance
- Corrosion resistance

Maintenance and Reuse

- Easy to decontaminate and discard disposable elements
- Easy to clean and replace parts in reusable PPE

Aesthetics

- Variety of styles and colors
- Customizable

Cost

- Product cost
- Total life-cycle cost
- Minimal environ-mental impact

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Background: Smart Shirt Research in J of the Textile Institute, vol. 89, 3, pp. 44-62, 1998.

Gathering User Needs

- Individual Surveys
- Focus Groups
- Information Gathering Process
  - User Profile
  - Training
  - Using the Device
  - Post-Use (Disposal)
  - Likes and Dislikes
  - Changes to Device
- Rank the Needs – Establish Priorities for Design

User Needs: Healthcare Workers

Step One: Define the Requirements

Functionality (Protection)	• Provide a barrier against transfer of
	  • Microorganisms
	  • Body Fluids
	  • Particulate Material

Usability	• Breathable • Prevent Face Seal Leakage • Ease of Donning and Doffing • Reusable after Decontamination and Laundering • Minimal Impact on Job Performance • Does not impair communication
Wearability	• Lightweight • Comfortable
Shape Conformability (Dimensional Stability)	• Conform to Desired Facial Shape • Dimensional Stability during Repeated Use and after Laundering

Durability	• Flexural Endurance
	• Mechanical Strength
	  o Tear
	  o Tensile/Shear
	  o Burst
	• Abrasion Resistance

Maintainability	• Ease of Care including
	  • Ease of Decontamination
	  • Ease of Laundering

Manufacturability	• Ease of Fabrication • Compatible with Standard Manufacturing Machinery
Affordability	• Material Cost • Manufacturing Cost

Step Two: What to How

Attribute (What) / Parameter (How)	Particulate Filtration Efficiency	Bacterial Filtration Efficiency	Degree of Leakage	Fluid Resistance	Pressure Drop (• P)	Force Exerted by Straps	Mass of Respirator	Moisture Absorption (Wickability)	Shape Conformance	Slip Resistance	Vibration Resistance	Shock Absorption	Time to Put Mask On	Time to Take Mask Off	Length of Use
	%	%	%		in	N	oz	%					sec	sec	hr
Protection (Functionality)															
Filtration Efficiency	x	x													
Face Seal Leakage			x						x	x	x	x			
Fluid Resistance				x											
Comfort															
Breathability					x										
Prolonged Use Without Discomfort					x	x	x	x							
Tightness of Strap						x									
Weight							x								
Usability															
Range of Facial Profiles															
Impairment of Communication															
Sweating															
Ease of Donning															
Ease of Doffing															
Duration of Use															
Maintenance and Reuse															
Ease of Decontamination															
Reusability															
Durability															
Length of Use (Hours/Days)															
Cost															
Unit Price															
Disposal Cost															
Aesthetics															
Colors															
Styles/Shape															

What to How – A Closer Look

Metrics

Attribute (What) / Parameter (How)	Particulate Filtration Efficiency	Bacterial Filtration Efficiency	Degree of Leakage	Fluid Resistance	Pressure Drop (• P)	Force Exerted by Straps	Mass of Respirator	Moisture Absorption (Wickability)	Shape Conformance	Slip Resistance	Vibration Resistance	Shock Absorption	Time to Put Mask On	Time to Take Mask Off	Length of Use
	%	%	%		in	N	oz	%					sec	sec	hr
Protection (Functionality)															
Filtration Efficiency	x	x													
Face Seal Leakage			x						x	x	x	x			
Fluid Resistance				x											
Comfort															
Breathability					x										
Prolonged Use Without Discomfort					x	x	x	x							
Tightness of Strap						x									
Weight							x								

Metrics

- BFE (Bacterial Filtration Efficiency) measures the percent efficiency at which the face mask filters bacteria passing through the mask.
- PFE (Particulate Filtration Efficiency) measures the percent efficiency at which the face mask filters particulate matter passing through the mask.
- ΔP (Breathability) is the pressure drop across a facemask, expressed in mm water/cm¾. The higher the Delta P, the more difficult the mask is to breathe through.
- Fluid resistance is defined as the ability of a facemask's material construction to minimize fluids from traveling through the material and potentially coming into contact with the user of the facemask. Fluid resistance helps reduce potential exposure to blood and body fluids caused from splashes, spray or spatter.

Source: The Basics of Surgical Mask Selection

By Dianne Rawson, RN, MA

3M Corporation

Characteristics of the Face-Seal Interface

- Shape Conformance (Flexibility)
- Slip Resistance
- Shock Absorption
- Vibration Resistance
- Comfort
- Texture
- Hypo-Allergenic

Easy to Put On, Stay in Place → Prevent Leakage

Step Three: Assess the Competition (Benchmarking)

10 = Always; 5 = Sometimes; 1 = Never

Attribute	Duck-Bill	Flat-fold	Fan-Fold	Cup	Surgical N95 SurgicalMask	Surgical Mask
Protection (Functionality)						
Filtration Efficiency						
Face Seal Leakage						
Fluid Resistance						
Comfort						
Breathability						
Prolonged Use Without Discomfort						
Tightness of Strap						
Weight						
Usability						
Range of Facial Profiles						
Impairment of Communication						
Sweating						
Ease of Donning						
Ease of Doffing						
Duration of Use						

Styles of Filtering Facepiece Respirators

Duck-bill
Kimberly-Clark

Flat-fold
3M 9211

Flat-fold
MSA

Cup
Gerson 2747

Fan-fold
Alpha-Protech

Surgical N95
Moldex 3100

Surgical Mask
Kimberly-Clark

Step Four: Define the Specifications

Respirator Attributes and Design Metrics				
Based on the Comparative Analysis and Benchmarking data, enter the Ideal and Acceptable Values for each Metric; provide the link to the path forward/action plan to address this design attribute.				
Metric	**Unit of Measure**	**Ideal Value**	**Acceptable Value**	**Path Forward - What will be done?**
Particulate Filtration Efficiency	**%**			
Bacterial Filtration Efficiency	**%**			
Degree of Leakage	**%**			
Fluid Resistance				
Pressure Drop (• P)	**in**			
Force Exerted by Straps	**N**			
Mass of Respirator	**oz**			
Moisture Absorption (Wickability)	**%**			
Shape Conformance				
Slip Resistance				
Vibration Resistance				
Shock Absorption				
Time to Put Mask On	**sec**			
Time to Take Mask Off	**sec**			
Length of Use	**hr**			

Step 5: Bring It All Together

Requirements → Translate Into → **Properties** → Are Achieved Through → **Materials & Fabrication Technologies** → By Applying These → **Design Parameters**

Mask Performance Requirements

- Functionality
- Usability
- Wearability
- Shape Conformability
- Durability
- Maintainability
- Manufacturability
- Affordability

Desired Properties

<u>*Barrier Properties*</u>

- Resistance to Transmission of
  - Microorganisms
  - Particulates
  - Fluids

<u>*Comfort Properties*</u>

- Hand
- Air Permeability
- Moisture Absorption
- Stretchability
- Bending Rigidity
- Weight
- Tensile Strength & Modulus
- Form-Fitting
- Manufacturability
- Cost

Lead To

Design

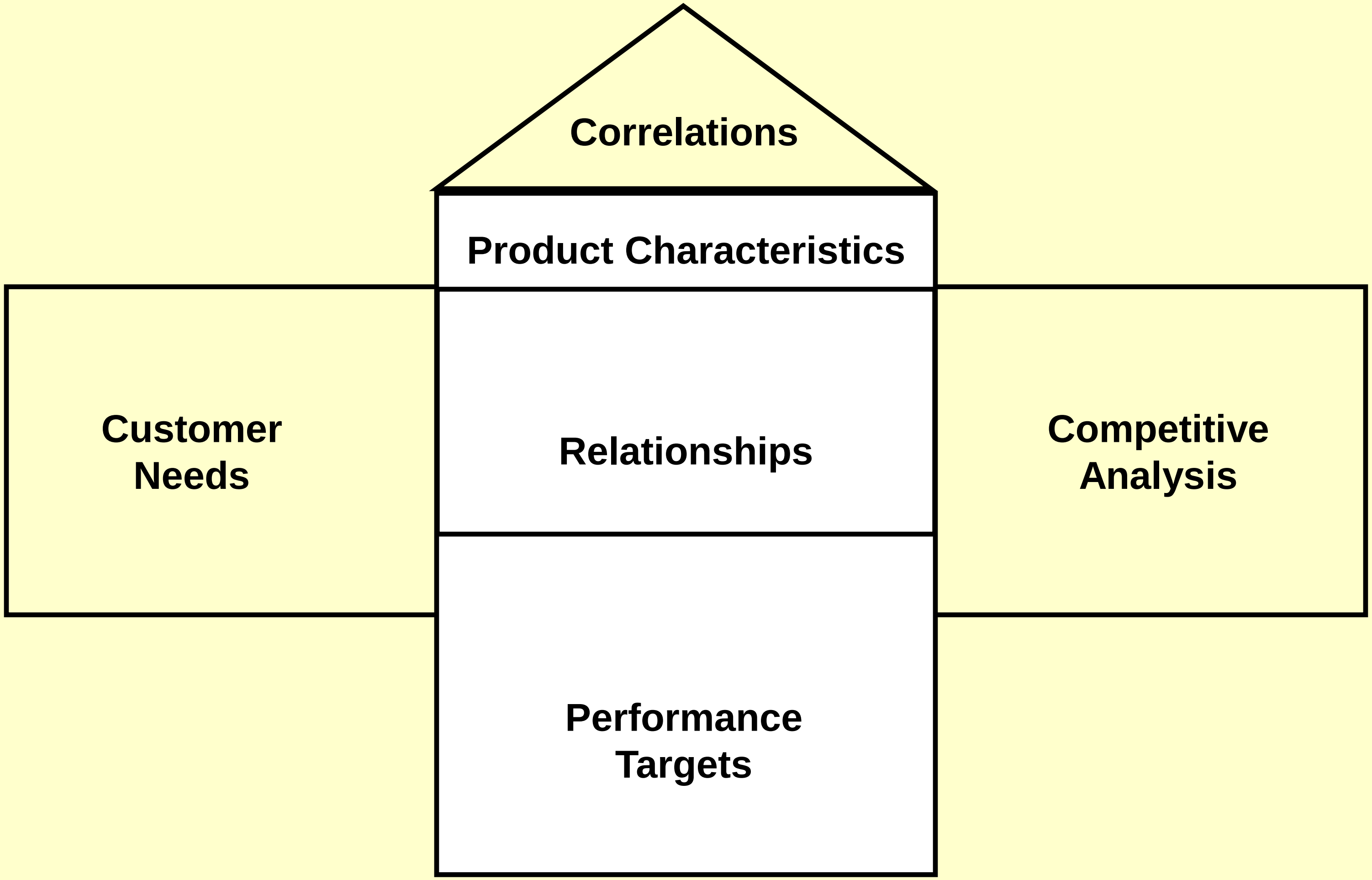
- Barrier Component (BC)
- Comfort Component (CC)
- Form-Fitting Component (FFC)

Materials	*Design Parameters*
<u>*Barrier Component (BC)*</u> •Polypropylene Filter Media •Electrostatic Charged Filters •Textile Fibers	Filter Density Filter Composition
<u>*Comfort Component (CC)*</u> •Meraklon (Polypropylene) •Microdenier Polyester Blend	Fiber Length, Fineness, Strength, Elongation, Moisture Absorption, Density, Friction, Cross-Sectional Shape
<u>*Form-Fitting Component (FFC)*</u>	Strength, Elongation, Fineness, Creep/Elastic Recovery

Manufacturing Technologies	*Design Parameters*
Novel	Warp/Weft Density, Weave Structure, Warp/Weft Yarn Count
Nonwoven	Matt Density, Type of Bonding

Mask Assembly	*Design Parameters*
Cutting, Sewing Straps, Filter Integration	Number of Layers, Lay-up Orientation, Filter-Structure Composition

Building The House of *i*Respirator …



Concept to Market: Making it Happen

- The Key Design Drivers

Evidence-Based User Requirements Analysis

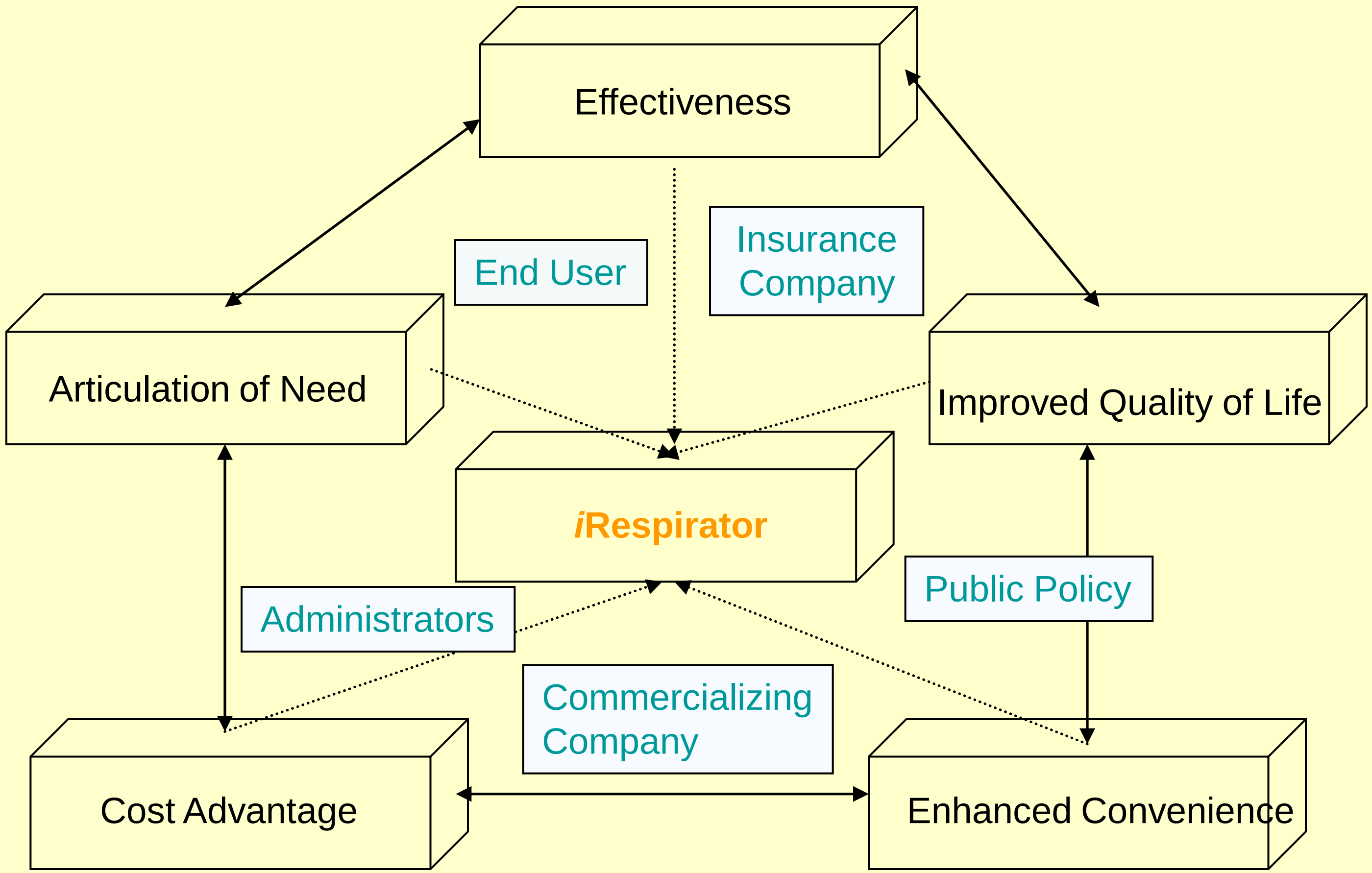
Design Realization

Field Use and Evaluation

Market Introduction

Post-Market Surveillance

An Integrated View: Coming Together



Technology Success Factors

- Success of Product in Market Depends on:
  - Effectiveness in Understanding User’s Needs and Meeting Them
  - Reduction in Cost of Current Solutions to be Supplanted
  - Improvement in the Quality of Service or Performance
  - Enhancement of the User’s Convenience
  - Adoption of Innovation – E.M. Rogers
    - Is there a Relative Advantage?
    - Does it Ensure Compatibility?
    - Degree of Complexity
    - Observability: Opportunity to Observe the Product in Use
    - Trialability: Opportunity to test or try out the Product
  - Apple’s Newton – A Failure :: iPAD – A Success (Before its Birth)!

The Path Forward

- Innovation & Systems Approach: Critical for Success
- Goal: Ideal Design for the Optimal Cost
- Modular Design – Product Flexibility
- Breakthrough Thinking – Important for Making Significant Progress in Respiratory Protection
- The Engineering Design Paradigm = Creative + Structured Thinking
- “Doing Well by Doing Good”

Acknowledgments

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- Fellow Members for their Observations!
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